

directed to the Group IV of the non-elected claims in the parent application, U.S. Serial No. 09/028,655, filed February 24, 1999. Support for reciting "CXXX", "XCXX", "XXCX", or "XXXC" box in claim 13 can be found, *inter alia*, at page 11, line 30 through page 12, line 6 of the present specification. Support for reciting "an animal or a plant", "a mammal", "a human", or "a non-human primate" in claims 18-21 can be found, *inter alia*, at page 3, lines 14-14 and at page 15, lines 3-5 of the present specification. Therefore, the above-described amendments do not introduce any new matter into the present application.

Rightsel, even in view of Van der Pyl, does not inherently disclose, teach or suggest that the "anti-viral" activity and the farnesylation inhibition activity of gliotoxin and acetylgliotoxin are the same

In the prosecution of the parent application, Rightsel et al., Nature (1964) 204:1333-1334 ("Rightsel") was cited as a prior art. It is submitted herein that Rightsel does not inherently disclose, teach or suggest the presently pending claims for several reasons. First, Rightsel provides no true measure of actual virus production, titers, genome levels, etc. The "anti-viral" activity measured in Rightsel is simply a visual assessment of cell appearance and is nothing more than a host cell response to the presence of viral proteins. The cytopathic effect described in Rightsel can best be viewed as a morphologic correlation to early cytotoxicity of the treatment with gliotoxin and acetylgliotoxin. This cytotoxicity could be inhibited by numerous conditions, e.g., pH changes, protein synthesis inhibition, etc., none of which would have any relevance to the presently claimed methods.

In addition, even assuming, *arguendo*, that Rightsel discloses, teaches or suggests the kind of anti-viral activity contemplated by the presently pending methods, Rightsel still does not disclose, teach or suggest, at least explicitly, that gliotoxin and acetylgliotoxin have any farnesylation inhibiting activity. Van der Pyl et al., J. Antibiotics (1992) 45:1802-1805 ("Van der Pyl"), which is not a prior art to the present application, was used as an extrinsic evidence to show that Rightsel inherently discloses, teaches or suggests that gliotoxin and acetylgliotoxin have farnesylation inhibiting activity and this farnesylation inhibiting activity is the basis for the arguably disclosed or taught "anti-viral activity" of gliotoxin and acetylgliotoxin. However, such a conclusion cannot be reached in view of the total disclosure of Rightsel and Van der Pyl pursuant to the legal precedents on the "inherency" issue.

The Court in Continental Can Co. USA, v. Monsanto Co., 948 F.2d 1264; 20 U.S.P.Q.2d 1746 (Fed. Cir. 1991) (Exhibit A) stated:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 322, 326 (CCPA 1981) (Exhibit B) (quoting *Hansgrig v. Kemmer*, 102 F.2d 212, 214, 40 U.S.P.Q. 665, 667 (CCPA 1939) (Exhibit C) provides:

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Rightsel discloses or teaches that gliotoxin and acetylgliotoxin have certain "activity" against, besides HSV and influenza viruses, poliovirus, which is not a prenylated virus. This result indicates that whatever this activity is, it has nothing to do with farnesylation inhibiting activity. In addition, as discussed in the Amendment under 37 C.F.R. § 1.116, filed April 7, 2000 in connection with the parent application, Van der Pyl, if not conclusively proves, strongly indicates that the "anti-viral" activity and farnesylation inhibiting activity of gliotoxin and acetylgliotoxin are two separate and distinct activities. Further, Van der Pyl actually indicates that the "anti-viral activity" and the farnesylation inhibiting activity of gliotoxin and acetylgliotoxin are two mutually exclusive activities, *i.e.*, the oxidized forms have the "anti-viral" activity while the reduced forms have the farnesylation inhibiting activity. Taken as a whole, it cannot be said that Rightsel, even in view of Van der Pyl, necessarily discloses or teaches to the skilled artisans that the "anti-viral" activity and farnesylation inhibiting activity of gliotoxin and acetylgliotoxin are the same one because there exists plenty of contrary evidence. Rightsel, in view of Van der Pyl, may possibly or even probably discloses or teaches that such is the case, but as the CCPA and Federal Circuit consistently held, mere "probabilities or possibilities" is not sufficient to establish "inherency" by extrinsic evidence.

CONCLUSION

In view of the above remarks, it is respectfully submitted that the pending claims 13-21 are in form of allowance. Early allowance of the pending claims 13-21 are earnestly requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **240042052403**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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